MAY 2 2 2001

PARADIGM MEDICAL INDUSTRIES INC.,

2355 South 1070 West
Salt Lake City, Utah 84119
(801) 977-8970
(801) 977-8973 (fax)
Tracy S. Best, Manager, Regulatory Affairs and Quality Assurance

K003318

Preparation Date: October 18, 2000

Summary of Safety and Effectiveness for the:

Trade Name: Photon Workstation w/810 nm module

Common Name: Solid State Diode, Frequency Doubled, 810 nm

Classification Name: Ophthalmic & General Surgery Photocoagulator

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Legally Marketed Predicate Devices for Substantial Equivalence:

* D10 810nm Diode Laser System Manufactured by CeramOptec, Inc.

* OcuLight SL & SLx, Manufactured by IRIDEX (IRIS Medical), Inc.

Rationale for SE: The D10 and the OcuLight SLx (SL) Lasers and Delivery Devices share similar indications for use in Ophthalmology, General and Plastic Surgery, Dermatology and others. Similar design features include; wavelengths, beam integrity, and cooling type. Control systems such as interlock devices, (safety systems) and displays are constantly monitored for user intervention. Functional features such as; delivery power, pulse rates, energy type, and spot sizes are also similar to the aforementioned devices. *Also see Attachment "A"* Comparison Chart of Equivalence.

Description of Submitted Device:

The Photon Modular Workstation w/810 nm Laser System is a combination surgical instrument for use in the multi-application of Ophthalmology and General and Plastic Surgery. The addition of a pre-approved (currently marketed OEM), fully contained laser module, to be controlled by the Photon Surgical Platform is the basis of this submission. The laser light is produced by Solid State Diode technology. With a output power of up to 3 Watts and utilizing 810 nm infrared laser light, additional indications for use are warranted. Indications for use are supported by readily available (OEM) SMA Connector Type fiber optic delivery devices. They include endoprobes, bent and straight of different gauges fiber, as well as, Laser Indirect Ophthalmoscopes, slit lamp adaptors for the delivery of laser energy through a slit lamp and surgical microscope and contact (ocular) probes. The delivery devices mentioned are compatible with the applied for indications of use.

Intended Uses of the Photon Workstation w/810 Laser:

See attachment "B" for a complete listing of indicated uses.

Technological Characteristics and Substantial Equivalence:

The D10 primary energy output source is a solid state diode that produces infrared laser light that is delivered to the patient for purpose of treatment. This system has various timing features for interval, and duration. The Aiming Beam has a Visible Red Diode @ 630-680 nm wavelength. The solid state design, for all mentioned in this submission, makes the laser less prone to requiring maintenance. The efficient operation of the diode makes lasers more reliable.

The OcuLight SL & SLx Laser Systems use an infrared (808 nm) semiconductor diode laser light as the primary source of energy. The converted energy is in the 800 ±10nm. The OcuLight Laser Systems deliver similar wavelength, similar power, spot sizes and pulse duration to the purposed Photon Workstation w/810 nm. The OcuLight has a full line of accessories for the delivery and treatment of laser energy. The aiming beam diode is a visible red diode @ 650-670nm. The analog Pulsed Diode is similar to the control of a digital pulsed diode, both are controlled by software.

Nonclinical Performance Data

None

Clinical Performance Data

None

Conclusion:

The Photon Modular Workstation w/810 Laser is substantially equivalent to other existing surgical laser systems in commercial distribution. The Photon concept is built on the already approved Precisionist Thirty Thousand ref: K953447 Ultrasound Surgical Device. The laser module is an OEM laser that is integrated into and enclosed in the Photon (Ocular Surgical) System. The laser has internal software that communicates with the Photon and accept commands. This allows the flexibility for physicians to add modules to already purchased capitol equipment. The safety systems of the laser are integrated within the chassis of the Photon Workstation and comply with requirements of 21 CFR 1040, *Safety Systems.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Tracy S. Best
Manager, Regulatory Affairs
and Quality Assurance
Paradigm Medical Industries, Inc.
2355 South 1070 West
Salt Lake City, Utah 84119

Re: K003318
Trade Name: Photon Workstation with 810 nm Module
Regulation Number: 874.4810
Regulatory Class: II
Product Code: GEX
Dated: March 20, 2001
Received: March 21, 2001

Dear Mr. Best:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003318

Device Name: Photon Workstation System w/810 nm

Indications For Use:

Ophthalmology: Transcleral Cyclophotocoagulation
Ablation of the Ciliary Process for the Reduction of IOP

Transcleral Endo Cyclophotocoagulation
Retinal Photocoagulation

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003318

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)